Biotechnology Risk Assessment Research Grants Program

FY 2002 Request for Applications

PROPOSAL DEADLINE:

February 15, 2002

U.S. Department of Agriculture

Cooperative State Research, Education and Extension Service

SUMMARY: The Agricultural Research Service (ARS) and the Cooperative State Research, Education, and Extension Service (CSREES) announce the availability of grant funds and request applications for the Biotechnology Risk Assessment Research Grants Program (BRARGP) for fiscal year (FY) 2002 to support environmental assessment research concerning the introduction of genetically engineered organisms into the environment. The amount available for support of this program in FY 2002 is approximately $1.5 million.

This notice identifies the objectives for BRARGP projects, the eligibility criteria for projects and applicants, and the application forms and associated instructions needed to apply for a BRARGP grant. CSREES additionally requests stakeholder input from any interested party for use in the development of the next Request for Applications (RFA) for this program.

DATES: Applications must be received by close of business (COB) on February 15, 2002 (5:00 p.m. Eastern Time). Applications received after this deadline will not be considered for funding. Comments regarding this RFA are requested within six months from the issuance of this notice. Comments received after that date will be considered to the extent practicable.

ADDRESSES:. The address for hand-delivered applications or applications submitted using an express mail or overnight courier service is: Biotechnology Risk Assessment Research Grants Program; c/o Proposal Services Unit; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, S.W.; Washington, D.C. 20024; Telephone: (202)401-5048.

Applications sent via the U.S. Postal Service must be sent to the following address: Biotechnology Risk Assessment Research Grants Program; c/o Proposal Services Unit; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, S.W.; Washington, D.C. 20250-2245.

Written stakeholder comments should be submitted by mail to: Policy and Program Liaison Staff; Office of Extramural Programs; USDA-CSREES; STOP 2299; 1400 Independence Avenue, S.W.; Washington, D.C. 20250-2299; or via e-mail to: RFP-OEP@reeusda.gov. (This e-mail address is intended only for receiving comments regarding this RFA and not requesting information or forms.) In your comments, please state that you are responding to the Biotechnology Risk Assessment Research Grants Program RFA.

FOR FURTHER INFORMATION CONTACT: Applicants and other interested parties are encouraged to contact Dr. Deborah Sheely; Program Director, Cooperative State Research, Education and Extension Service; U.S. Department of Agriculture; Stop 2241; 1400 Independence Avenue, S.W.; Washington, DC 20250-2241; telephone: 202-401-1924; fax: 202-401-1782; email: dsheely@reeusda.gov or Dr. John Radin, National Program Leader, Plant Physiology and Cotton; Agricultural Research Service; U.S. Department of Agriculture; George Washington Carver Center, Room 4-2232; 5601 Sunnyside Avenue; Beltsville, MD 20705-5139; telephone 301-504-5450; fax 301- 504-6191; email: jwr@ars.usda.gov.

STAKEHOLDER INPUT: CSREES is requesting comments regarding this RFA from any interested party. These comments will be considered in the development of the next RFA for the

program. Such comments will be used to meet the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7613(c)(2)). This section requires the Secretary to solicit and consider input on a current RFA from persons who conduct or use agricultural research, education and extension for use in formulating future RFA's for competitive programs. Comments should be submitted as provided for in the **Addresses** and **Dates** portions of this Notice.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE: This program is listed in the Catalog of Federal Domestic Assistance under 10.219, Biotechnology Risk Assessment Research.

Table of Contents

PART I--GENERAL INFORMATION

A. Legislative Authority and Background

The authority for the Program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921). The administrative regulations for this program are found at 7 CFR part 3415.

B. Purpose, Priorities and Fund Availability

The purpose of the Program is to assist Federal regulatory agencies in making science-based decisions about the effects of introducing into the environment genetically modified organisms, including plants, microorganisms (including fungi, bacteria, and viruses), arthropods, fish, birds, mammals and other animals excluding humans. Investigations of effects on both managed and natural environments are relevant. The Program accomplishes this purpose by providing scientific information derived from the risk assessment research that it funds. Research applications submitted to the Program must be applicable to the purpose of the Program to be considered.

There is no commitment by USDA to fund any particular proposal or to make a specific number of awards. Approximately $1.5 million will be available to fund proposals in FY 2002. The agency intends to award these funds for project proposals in the targeted areas with no more than two awards for conference proposals. Applications are being solicited for the Biotechnology Risk Assessment Research Grants Program in the following component areas:

(1) Research relevant to assessing the effects of the introduction into the environment of genetically engineered organisms. Potential subject areas include but are not limited to: (a) research on the potential for recombination between plant viruses and plant-encoded viral transgenes; (b) research on the potential for non-target effects of introduced foreign gene products expressed in genetically modified plant-associated microorganisms (e.g., compounds in phyllosphere or rhizosphere-inhabiting bacteria) or in plants (e.g., Bacillus thuringiensis delta-endotoxin), especially in regard to persistence of the organisms and material in the environment, including their impact on beneficial or soil organisms and appropriate validated field or laboratory assays to measure significant effects on a broad range of beneficial species expected to be exposed in different genetically-engineered crops; (c) changes in ecosystem or agro-ecosystem function and composition; (d) research on gene flow from transgenic crops to related plants and exploration of factors influencing gene transfer rates. Gene flow experiments on crops with a high potential for outcrossing or for gene introgression into wild or weedy relatives (e.g., those with high rates of outcrossing and with overlapping habitats are of particular interest); (e) research on the role that insects and/or pathogens play in limiting populations of crops and weeds as this relates to acquisition of transgenic pest protection by crops and/or weeds; (f) research on how transgenic plants, especially grasses, that are resistant or tolerant to environmental stresses (such as drought or salt) affect land use practices (new habitats or tillage), water use (irrigation) patterns, and species displacement.

The data collected may include: survival; reproductive fitness; genetic stability (e.g., transgene retained during backcrossing); genetic recombination; horizontal gene transfer; loss of genetic diversity; or enhanced competitiveness. As long as the data gathered are relevant to the assessment of the effects of genetically modified organisms, the experiments need not utilize transgenic organisms. When feasible, measures of risk should include estimates of expected frequency and impact, and address the availability of effective mitigation measures to reduce or avoid impacts.

(2) Research on large-scale deployment of genetically engineered organisms, especially commercial uses of such organisms, with special reference to considerations that may not be revealed through small-scale evaluations and tests and may address cumulative effect concerns. Studies should attempt to project impacts over as large a spatial and temporal scale as feasible. Potential focus areas include but are not limited to: (a) studies of insects and viruses that have developed resistance to plants possessing transgenic protection from them. This may be done by monitoring locations where such plants are grown on a commercial scale or in large scale production. The analysis of resistant viral strains should include analyzing whether the strain arose via recombination between viral transgenes and the viral genome and an analysis of how the resistance was effected (e.g., changed coat protein with increased seed or insect vector transmissibility). The potential for transcapsidation in transgenic plants to alter seed transmission can be evaluated by comparing the levels of infected seed from transgenic plants inoculated with a virus, that could be transcapsidated, with seed from nontransgenic plants inoculated in a similar manner. Analysis should include the presence of satellite RNA (satRNA) which may replicate with the help of a suitable helper virus. Such projects should survey the production sites for two to three years; (b) studies to assess the relative impacts of agricultural management systems using transgenic vs. nontransgenic plants, especially insect resistant or herbicide tolerant plants, on biodiversity of agro-ecosystems. This could include changes in population dynamics and species diversity of nontarget arthropods (particularly beneficial predators, parasites, and pollinators), plants, mammals, avian or microbial species (including both pathogenic or beneficial fungi or bacteria associated with the crop plant). These studies should be conducted in such a way as to compare the impacts of transgenic plants to nontransgenic cultivars with otherwise similar phenotypes using the commonly recommended or adopted practices for tillage, irrigation, and control of pests or weeds. Also, effects of these plants on soil erosion or water quality could be included. Extensive documentation of agricultural practices will be a necessary component; and (c) monitoring for the occurrence of individual or stacked resistance traits in wild/weedy relatives of commercialized transgenic crops, and subsequently, any effects of such genes on fitness, competitiveness, and weediness.

(3) Research to assess the effects of transgenes in wild relatives of crop species. This research could evaluate the potential for unexpected fitness effects by comparing fitness characteristics in hybrids or introgressants between a transgenic line and the wild relative to hybrids or introgressants between the nontransgenic line and the wild relatives, or could evaluate fitness effects of the introduced trait by evaluating survival or reproductive success under natural conditions, or through planned competition experiments. Crop species could include those with compatible wild relatives in the U.S. which have been deregulated (e.g., rice, rapeseed, melon, and squash) or are being developed (e.g., sunflower, turfgrasses, and strawberry). Introduced

traits could include those that have potential effects on fitness (e.g., pest or disease resistance), or that have potential physiological or metabolic effects.

(4) Research to assess the effects of genetically engineered plants with "stacked" resistance genes or genes that confer broad resistance to insects or diseases. These genes may give recipient plants a greater selective advantage and lead to less predictable ecological consequences. Possible areas of research include, but are not limited to: (a) the impact of gene stacking on non-target species; (b) the effects of stacked genes on pest populations; (c) transmission and establishment of multiple resistance genes into weedy relatives; (d) influence of genetic factors such as linkage on the transmission and establishment of multiple genes; and (e) ecological importance in weedy hosts of pest complexes sufficiently variable as to require broad resistance or stacked genes for their control.

(5) Research to develop statistical methodology and evaluate current confinement practices used when field testing genetically modified organisms, especially plants.

(6) Research to assess the effects of transgene(s) in engineered arthropods and other invertebrates. This research could evaluate: (a) genotypic and phenotype transgene stability (including the transposon vector system) over multiple generations; (b) comparative mating competence or reproductive studies; (c) comparative behavior and biology studies including whether engineering alters host range; (d) an evaluation of the potential of horizontal transgene movement to parasites, predators, baculoviruses, pathogens, and endosymbionts of the engineered insect; (e) comparison of whether engineering alters behavioral or ecological interactions; and (f) determine whether engineering with traits that do not encode insecticidal resistance affects susceptibility or resistance to chemical or biological insecticides.

(7) The Program will, subject to resource availability, provide partial funding to organize a conference that brings together scientists, regulators, and others to review the science-based data relevant to risk assessment of genetically modified organisms released into the environment. The steering committee for the conference should include representatives from a variety of relevant scientific disciplines, such as ecology, population biology, pathology, production and resource management science, as well as educators, extension specialists and others, as appropriate. The goals of such a conference may include sharing of scientific information and identification of gaps in knowledge, and/or public education and outreach, among others. Publication of the proceedings will be required. The Program will fund a maximum of two conference proposals.

C. Eligibility

Applications may be submitted by any United States public or private research or educational institution or organization. Award recipients may subcontract to organizations not eligible to apply provided such organizations are necessary for the conduct of the project.

D. Indirect Costs

Section 1462 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3310) limits indirect costs for this program to 19 percent of total Federal funds provided under each award. Therefore the recovery of indirect costs under this program may not exceed the lesser of the institution's official negotiated indirect cost rate or the equivalent of 19 percent of total Federal funds awarded. Another method of calculating the maximum allowable is 23.456 percent of the total direct costs. (This limitation also applies to the recovery of indirect costs by any subawardee or subcontractor, and should be reflected in the subrecipient budget.) If no rate has been negotiated, a reasonable dollar amount (equivalent to or less than 19 percent of total Federal funds requested) in lieu of indirect costs may be requested, subject to approval by USDA.

E. Matching Requirements

No matching funds are required for grants awarded under the Biotechnology Risk Assessment Grants Program.

F. Funding Restrictions

Under the Biotechnology Risk Assessment Research Grants Program, the use of grant funds to plan, acquire, or construct a building or facility is not allowed. With prior approval, in accordance with the cost principles set forth in OMB Circular No. A-21, some grant funds may be used for minor alterations, renovations, or repairs deemed necessary to retrofit existing teaching spaces in order to carry out a funded project. However, requests to use grant funds for such purposes must demonstrate that the alterations, renovations, or repairs are incidental to the major purpose for which a grant is made.

G. Types of Applications

In FY 2002, applications may be submitted to the BRARGP Program as one of the following four types of requests:

(1) New application. This is a project application that has not been previously submitted to the BRARGP Program. All new applications will be reviewed competitively using the selection process and evaluation criteria described in Part IV--Review Process.

(2) Renewal application. This is a project application that requests additional funding for a project beyond the period that was approved in an original or amended award. Applications for renewed funding must contain the same information as required for new applications, and additionally must contain a Progress Report (see Project Description, Part III.B.6). Renewal applications must be received by the relevant due dates, will be evaluated in competition with other pending applications, and according to the same evaluation criteria as new applications.
(3) Resubmitted application. This is an application that had previously been submitted to the BRARGP Program but not funded. Project Directors (PD's) must respond to the previous review panel summary (see Response to Previous Review, Part III.B.5). Resubmitted

applications must be received by the relevant due dates, will be evaluated in competition with other pending applications, and according to the same evaluation criteria as new applications.

(4) Resubmitted renewal application. This is a project application that requests additional funding for a project beyond the period that was approved in the original award. In addition, this is an application that had previously been submitted for renewal to the BRARGP Program but not approved. Therefore, PD's must provide a Progress Report as required under the Project Description, Part III.B.6, and must respond to the previous review panel summary as required under Response to Previous Review, Part III.B.5. Resubmitted renewal applications must be received by the relevant due dates, will be evaluated in competition with other pending applications, and according to the same evaluation criteria as new applications.

PART II-- PROGRAM DESCRIPTION

A. Project Types

The program has no established maximum award size. However, budget requests should be limited to such sums as are necessary to successfully complete the proposed research. Award duration is limited to five years.

B. Program Description

CSREES and ARS will competitively award research grants to support science-based biotechnology regulation, thereby helping to address concerns about the effects of introducing genetically modified organisms into the environment and helping regulators to develop policies regarding such introduction.

The Program's emphasis is on risk assessment, which is defined as the science-based evaluation and interpretation of factual information in which a given hazard, if any, is identified, and the consequences associated with the hazard are explored. Research funded through this program will be relevant to risk assessment and the regulatory process. When evaluating transgenic organisms, regulators must answer the following four general questions: (1) is there a hazard (potential hazard identification)?; (2) how likely is the hazard to occur (quantifying the probability of occurrence)?; (3) what is the severity and extent of the hazard if it occurs (quantifying the effects)?; and (4) is there an effect above and beyond what might occur with an organism, with similar traits, developed using other technologies?

Although project directors are not required to perform actual risk assessments in the research they propose, they should design studies that will provide information useful to regulators for making science-based decisions in their assessments of genetically-modified organisms. Accordingly, program applicants are encouraged to address the following questions in their proposals: (1) What is the relevance of this research to the evaluation of transgenic organisms?; (2) What information will be provided by this research to help regulators adequately assess transgenic organisms?; and (3) How does this research model appropriate studies necessary to

identify and/or characterize hazards associated with introducing genetically-modified organisms into the environment?

The Program does not support risk management research, which is defined to include either (1) research aimed primarily at reducing effects of specific biotechnology-derived agents or (2) a policy and decision-making process that uses risk assessment data in deciding how to avoid or mitigate the consequences identified in a risk assessment. Proposals must be relevant to risk assessment to be eligible for this Program.

In addition to addressing the questions posed above, proposals must include a statement describing the relevance of the proposed project to one or more of the research topics requested in this RFA. In addition, proposals should include detailed descriptions of the experimental design and appropriate statistical analyses to be done.

Awards will not be made for clinical trials, commercial product development, product marketing strategies, or other research deemed not appropriate to risk assessment.

PART III--PREPARATION OF A PROPOSAL

A. Program Application Materials

Program application materials are available at the CSREES Funding Opportunities web site (http://www.reeusda.gov/1700/funding/ourfund.htm). If you do not have access to the web page or have trouble downloading material and you would like a hardcopy, you may contact the Proposal Services Unit, Office of Extramural Programs, USDA/CSREES at (202) 401-5048. When calling the Proposal Services Unit, please indicate that you are requesting the RFA and associated application forms for the Biotechnology Risk Assessment Research Grants Program. These materials also may be requested via Internet by sending a message with your name, mailing address (not e-mail) and phone number to psb@reeusda.gov. State that you want a copy of the RFA and the associated application forms for the Biotechnology Risk Assessment Research Grants Program.

B. Content of Proposals

The proposals should be prepared following the guidelines and the instructions below.
Each proposal must contain the following elements in the order indicated:

1. General

Use the following guidelines to prepare an application. Proper preparation of applications will assist reviewers in evaluating the merits of each application in a systematic, consistent fashion:

(a) Prepare the application on only one side of the page using standard size (8 1/2" x 11") white paper, one-inch margins, typed or word processed using no type smaller than 12 point font, and single or double spaced. Use an easily readable font face (e.g., Geneva, Helvetica, Times Roman).

(b) Number each page of the application sequentially, starting with the Project Description, including the budget pages, required forms, and any appendices.

(c) Staple the application in the upper left-hand corner. Do not bind. An original and 14 copies (15 total) must be submitted in one package.

(d) Include original illustrations (photographs, color prints, etc.) in all copies of the application to prevent loss of meaning through poor quality reproduction.

(e) The contents of the application should be assembled in the following order:

(1) Proposal Cover Page (Form CSREES-2002)
(2) Table of Contents
(3) Project Summary (Form CSREES-2003)
(4) Response to Previous Review
(5) Project Description
(6) References
(7) Appendices to Project Description
(8) Key Personnel
(9) Collaborative Arrangements (including Letters of Support)
(10) Conflict-of-Interest List (Form CSREES-2007)
(11) Budget (Form CSREES-2004)
(12) Budget Narrative
(13) Matching
(14) Current and Pending Support (Form CSREES-2005)
(15) Assurance Statement(s) (Form CSREES-2008)
(16) Compliance with the National Environmental Policy Act (NEPA) (Form CSREES-2006)
(17) Page B, Proposal Cover Page (Form CSREES-2002), Personal Data on Project Director

2. Proposal Cover Page (Form CSREES-2002)

Page A

Each copy of each grant application must contain a "Proposal Cover Page", Form CSREES-2002. One copy of the application, preferably the original, must contain the pen-and-ink signature(s) of the proposing PD's and the authorized organizational

representative (AOR), the individual who possesses the necessary authority to commit the organization's time and other relevant resources to the project. If there are more than four co-PD's for an application, please list additional co-PD's on a separate sheet of paper (with appropriate information and signatures) and attach to the Proposal Cover Page (Form CSREES-2002). Any proposed PD or co-PD whose signature does not appear on Form CSREES-2002 or attached additional sheets will not be listed on any resulting grant award. Complete both signature blocks located at the bottom of the "Proposal Cover Page" form. Please note that Form CSREES-2002 is comprised of two parts - Page A which is the "Proposal Cover Page" and Page B which is the "Personal Data on Project Director."

Form CSREES-2002 serves as a source document for the CSREES grant database; it is therefore important that it be accurately completed in its entirety, especially the e-mail addresses requested in blocks 4.c. and 18.c. However, the following items are highlighted as having a high potential for errors or misinterpretations:

(a) Type of Performing Organization (Block 6A and 6B). For block 6A, a check should be placed in the appropriate box to identify the type of organization which is the legal recipient named in block 1. Only one box should be checked. For block 6B, please check as many boxes that apply to the affiliation of the PD listed in block 16.

(b) Title of Proposed Project (Block 7). The title of the project must be brief (140-character maximum, including spaces), yet represent the major thrust of the effort being proposed. Project titles are read by a variety of nonscientific people; therefore, highly technical words or phraseology should be avoided where possible. In addition, introductory phrases such as "investigation of," "research on," "education for," or "outreach that" should not be used.

(c) Program to Which You Are Applying (Block 8). Enter Biotechnology Risk Assessment Research Grants Program.

(d) Type of Request (Block 14). Check the block for "new," "renewal," "resubmission," or "resubmitted renewal".

(e) Project Director (PD) (Blocks 16-19). Blocks 16-18 are used to identify the PD and Block 19 to identify co-PD's. If needed, additional co-PD's may be listed on a separate sheet of paper and attached to Form CSREES-2002, the Proposal Cover Page, with the applicable co-PD information and signatures. Listing multiple co-PD's, beyond those required for genuine collaboration, is discouraged.

(f) Other Possible Sponsors (Block 21). List the names or acronyms of all other public or private sponsors including other agencies within USDA to which your application has been or might be sent. In the event you decide to send your application to another organization or agency at a later date, you must inform the

identified CSREES program contact as soon as practicable. Submitting your application to other potential sponsors will not prejudice its review by CSREES; however, submitting the same (i.e., duplicate) application to another CSREES program is not permissible.

Page B

Page B should be submitted only with the original signature copy of the application and should be placed as the last page of the original copy of the application. This page contains personal data on the PD(s). CSREES requests this information in order to monitor the operation of its review and awards processes. This page will not be duplicated or used during the review process. Please note that failure to submit this information will in no way affect consideration of your application.

3. Table of Contents

For consistency and ease in locating information, each application must contain a detailed Table of Contents immediately following the proposal cover page. The Table of Contents should contain page numbers for each component of the application. Page numbering should begin with the first page of the Project Description.

4. Project Summary (Form CSREES-2003)

The application must contain a "Project Summary," Form CSREES-2003. The summary should be approximately 250 words, contained within the box, placed immediately after the Table of Contents, and not numbered. The names and affiliated organizations of all PD's and co-PD's should be listed on this form, in addition to the title of the project. The summary should be a self-contained, specific description of the activity to be undertaken and should focus on: overall project goal(s) and supporting objectives; plans to accomplish project goal(s); and relevance of the project to the goals of the BRARGP. The importance of a concise, informative Project Summary cannot be overemphasized. If there are more than four co-PD's for an application, please list additional co-PD's on a separate sheet of paper (with appropriate information) and attach to the Project Summary (Form CSREES-2003).

5. Response to Previous Review

This requirement only applies to "Resubmitted Applications" and "Resubmitted Renewal Applications" as described under Part I, H, "Types of Applications." Project Directors (PD's) must respond to the previous review panel summary on no more than one page, titled "RESPONSE TO PREVIOUS REVIEW," which is to be placed directly after the "Project Summary," Form CSREES-2003.

6. Project Description

PLEASE NOTE: The Project Description shall not exceed 18 pages of written text including figures and tables. This maximum has been established to ensure fair and equitable competition. The Project Description must include all of the following:
(a) Introduction. A clear statement of the long-term goal(s) and supporting objectives of the proposed project should preface the project description. The most significant published work in the field under consideration, including the work of key project personnel on the current application, should be reviewed. The current status of research in the particular scientific field also should be described. All work cited, including that of key personnel, should be referenced.

(b) Progress report. If the proposal is a renewal of an existing project supported under this program, include a clearly marked performance report describing results to date from the previous award. This section should contain the following information: (i) A comparison of actual accomplishments with the goals established for the previous award; (ii) The reasons established goals were not met, if applicable; and (iii) A listing of any publications resulting from the award. Copies of reprints or preprints may be appended to the proposal if desired.

(c) Rationale and significance. Present concisely the rationale behind the proposed project. The objectives' specific relationship and relevance to the area in which an application is submitted and the objectives' specific relationship and relevance to potential regulatory issues of United States biotechnology research should be shown clearly. Any novel ideas or contributions that the proposed project offers also should be discussed in this section.

(d) Experimental plan. The hypotheses or questions being asked and the methodology to be applied to the proposed project should be stated explicitly. Specifically, this section must include: (1) A description of the investigations and/or experiments proposed and the sequence in which the investigations or experiments are to be performed; (2) Techniques to be used in carrying out the proposed project, including the feasibility of the techniques; (3) Results expected; (4) Means by which experimental data will be analyzed or interpreted; (5) Pitfalls that may be encountered; (6) Limitations to proposed procedures; and (7) Tentative schedule for conducting major steps involved in these investigations and/or experiments.

In describing the experimental plan, the applicant must explain fully any materials, procedures, situations, or activities that may be hazardous to personnel (whether or not they are directly related to a particular phase of the proposed project), along with an outline of precautions to be exercised to avoid or mitigate the effects of such hazards.

(e) Facilities and equipment. All facilities and major items of equipment that are available for use or assignment to the proposed research project during the requested period of support should be described. In addition, items of nonexpendable equipment necessary to conduct and successfully conclude the proposed project should be listed.

7. References

All references to works cited should be complete, including titles and all co-authors, and should conform to an acceptable journal format. References are not considered in the page-limitation for the Project Description.

8. Appendices to Project Description

Appendices to the Project Description are allowed if they are directly germane to the proposed project. The addition of appendices should not be used to circumvent the text and/or figures and tables page limitations.

9. Key Personnel

The following should be included, as applicable:

(a) The roles and responsibilities of each PD and/or collaborator should be clearly described; and

(b) The vitae of the PD and each co-PD, senior associate, and other professional personnel. This section should include vitae of all key persons who are expected to work on the project, whether or not CSREES funds are sought for their support. The vitae should be limited to two (2) pages each in length, excluding publications listings. The vitae should include a presentation of academic and research credentials, as applicable, e.g., earned degrees, teaching experience, employment history, professional activities, honors and awards, and grants received. A chronological list of **all** publications in **refereed journals** during the past **four (4) years,** including those in press, must be provided for each project member for whom a curriculum vitae is provided. Also list only those **non-refereed** technical publications that have **relevance** to the proposed project. All authors should be listed in the same order as they appear on each paper cited, along with the title and complete reference as these usually appear in journals.

10. Collaborative Arrangements

If it will be necessary to enter into formal consulting or collaborative arrangements with others, such arrangements should be fully explained and justified. If the consultant(s) or collaborator(s) are known at the time of application, a vitae or resume should be provided. In addition, evidence (e.g., letter of support) should be provided that the collaborators involved have agreed to render these services. The applicant also will be required to provide additional information on consultants and collaborators in the budget portion of the application. See instructions in the application forms for completing Form CSREES-2004, Budget.

11. Conflict-of-Interest List (Form CSREES-2007)

A "Conflict-of-Interest List," Form CSREES-2007, must be provided for all individuals who have submitted a vitae in response to item 9.(b) of this part. Each Form CSREES-2007 should list alphabetically, by the last names, the full names of the individuals in the following categories: (a) All co-authors on publications within the past four years, including pending publications and submissions; (b) all collaborators on projects within the past four years, including current and planned collaborations; (c) all thesis or postdoctoral advisees/advisors within the past four years; and (d) all persons in your field with whom you have had a consulting or financial arrangement within the past four years, who stand to gain by seeing the project funded. This form is necessary to assist program staff in excluding from application review those individuals who have conflicts of interest with the personnel in the grant application. The program contact must be informed of any additional conflicts of interest that arise after the application is submitted.

12. Budget

a. General

(1) Budget Form (Form CSREES-2004)

Prepare the Budget, Form CSREES-2004, in accordance with instructions provided with the application forms. A budget form is required for each year of requested support. In addition, a cumulative budget is required detailing the requested total support for the overall project period. The budget form may be reproduced as needed by applicants. Funds may be requested under any of the categories listed on the form, provided that the item or service for which support is requested is allowable under the authorizing legislation, the applicable statutes, regulations, and Federal cost principles, and these program guidelines, and can be justified as necessary for the successful conduct of the proposed project. Applicants also must include a budget narrative to justify their budget requests (see section b. below.)

(2) Indirect Costs

Section 1462 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3310) limits indirect costs for this program to 19 percent of total Federal funds provided under each award. Therefore the recovery of indirect costs under this program may not exceed the lesser of the institution's official negotiated indirect cost rate or the equivalent of 19 percent of total Federal funds awarded. Another method of calculating the maximum allowable is 23.456 percent of the total direct costs. (This limitation also applies to the recovery of indirect costs by any subawardee or subcontractor, and should be reflected in the subrecipient budget.) If no rate has been negotiated, a reasonable dollar amount (equivalent to or less than 19 percent of total Federal funds requested) in lieu of indirect costs may be requested, subject to approval by USDA.

(3) Matching

There is no matching requirement for this grant program.

b. Budget Narrative

All budget categories, with the exception of Indirect Costs, for which support is requested, must be individually listed (with costs) in the same order as the budget and justified on a separate sheet of paper and placed immediately behind the Budget form.

c. Matching Funds

There is no matching requirement for this grant program.

13. Current and Pending Support (Form CSREES-2005)

All applications must contain Form CSREES-2005 listing other current public or private support (including in-house support) to which personnel (i.e., individuals submitting a vitae in response to item 9.(b) of this part) identified in the application have committed portions of their time, whether or not salary support for person(s) involved is included in the budget. Please follow the instructions provided on this form. Concurrent submission of identical or similar applications to the possible sponsors will not prejudice application review or evaluation by the CSREES. However, an application that duplicates or overlaps substantially with an application already reviewed and funded (or to be funded) by another organization or agency will not be funded under this program. **Please note that the project being proposed should be included in the pending section of the form.**

14. Assurance Statement(s) (Form CSREES-2008)

A number of situations encountered in the conduct of projects require special assurances, supporting documentation, etc., before funding can be approved for the project. In addition to any other situation that may exist with regard to a particular project, applications involving any of the following elements must comply with the additional requirements as applicable.

a. Recombinant DNA or RNA Research

As stated in 7 CFR Part 3015.205 (b)(3), all key personnel identified in the application and all endorsing officials of the proposing organization are required to comply with the guidelines established by the National Institutes of Health entitled, "Guidelines for Research Involving Recombinant DNA Molecules," as revised. If your project proposes to use recombinant DNA or RNA techniques, you must so indicate by checking the "yes" box in Block 20 of Form CSREES-2002 (the Proposal Cover Page) and by completing Section A of Form CSREES-2008. For applicable applications recommended for funding, Institutional Biosafety Committee approval is required before CSREES funds will be released. Please refer to the application forms for further instructions.

b. Animal Care

Responsibility for the humane care and treatment of live vertebrate animals used in any grant project supported with funds provided by CSREES rests with the performing organization. Where a project involves the use of living vertebrate animals for experimental purposes, all key personnel identified in an application and all endorsing officials of the proposing organization are required to comply with the applicable provisions of the Animal Welfare Act of 1966, as amended (7 U.S.C. 2131 et seq.), and the regulations promulgated thereunder by the Secretary in 9 CFR Parts 1, 2, 3, and 4 pertaining to the care, handling, and treatment of these animals. If your project will involve these animals, you should check "yes" in block 20 of Form CSREES-2002 and complete Section B of Form CSREES-2008. In the event a project involving the use of live vertebrate animals results in a grant award, funds will be released only after the Institutional Animal Care and Use Committee has approved the project. Please refer to the application forms for further instructions.

c. Protection of Human Subjects

Responsibility for safeguarding the rights and welfare of human subjects used in any grant project supported with funds provided by CSREES rests with the performing organization. Guidance on this issue is contained in the National Research Act, Pub. L. No. 93-348, as amended, and implementing regulations promulgated by the Department under 7 CFR Part 1c. If you propose to use human subjects in your project, you should check the "yes" box in Block 20 of Form CSREES-2002 and complete Section C of Form CSREES-2008. Please refer to the application forms for additional instructions.

15. Certifications

Note that by signing Form CSREES-2002 the applicant is providing the certifications required by 7 CFR Part 3017, regarding Debarment and Suspension and Drug-Free Workplace, and 7 CFR Part 3018, regarding Lobbying. The certification forms are included in the application package for informational purposes only. These forms should not be submitted with the application since by signing Form CSREES-2002 your organization is providing the required certifications. If the project will involve a subcontractor or consultant, the subcontractor/consultant should submit a Form AD-1048, Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions, to the grantee organization for retention in their records. This form should not be submitted to USDA.

16. Compliance with the National Environmental Policy Act (NEPA) (Form CSREES-2006)

As outlined in 7 CFR Part 3407 (the Cooperative State Research, Education, and Extension Service regulations implementing NEPA), the environmental data for any proposed project is to be provided to CSREES so that CSREES may determine whether any further action is needed. In some cases, however, the preparation of environmental data may not be required. Certain categories of actions are excluded from the requirements of NEPA.

In order for CSREES to determine whether any further action is needed with respect to NEPA, pertinent information regarding the possible environmental impacts of a particular project is necessary; therefore, Form CSREES-2006, "NEPA Exclusions Form," must be included in the application indicating whether the applicant is of the opinion that the project falls within a categorical exclusion and the reasons therefore. If it is the applicant's opinion that the proposed project falls within the categorical exclusions, the specific exclusion(s) must be identified.

Even though a project may fall within the categorical exclusions, CSREES may determine that an Environmental Assessment or an Environmental Impact Statement is necessary for an activity, if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present which may cause such activity to have a significant environmental effect.

C. Submission of Applications

1. When to Submit (Deadline Date)

Applications must be received by COB on **February 15, 2002** (5:00 p.m. Eastern Time). Applications received after this deadline will not be considered for funding.

2. What to Submit

An original and 14 copies must be submitted. All copies of the application must be submitted in one package.

3. Where to Submit

Applicants are strongly encouraged to submit completed applications via overnight mail or delivery service to ensure timely receipt by the USDA. The address for hand-delivered applications or applications submitted using an express mail or overnight courier service is:

Biotechnology Risk Assessment Research Grants Program
c/o Proposal Services Unit
Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture
Room 1307, Waterfront Centre
800 9th Street, S.W.
Washington, D.C. 20024

Telephone: (202) 401-5048

Applications sent via the U.S. Postal Service must be sent to the following address:

Biotechnology Risk Assessment Research Grants Program
c/o Proposal Services Unit
Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture
STOP 2245
1400 Independence Avenue, S.W.
Washington, D.C. 20250-2245

D. Acknowledgment of Applications

The receipt of all applications will be acknowledged by e-mail. Therefore, applicants are strongly encouraged to provide accurate e-mail addresses, where designated, on the Form CSREES-2002. If the applicant's e-mail address is not indicated, CSREES will acknowledge receipt of the application by letter.

If the applicant does not receive an acknowledgment within 60 days of the submission deadline, please contact the program contact. Once the application has been assigned an application number, please cite that number on all future correspondence.

PART IV--REVIEW PROCESS

A. General

Each application will be evaluated in a 2-part process. First, each application will be screened to ensure that it meets the administrative requirements as set forth in this RFA. Second, applications that meet these requirements will be technically evaluated by a review panel.

Reviewers will be selected based upon training and experience in relevant scientific, extension, or education fields, taking into account the following factors: (a) The level of relevant formal scientific, technical education, or extension experience of the individual, as well as the extent to which an individual is engaged in relevant research, education, or extension activities; (b) the need to include as reviewers experts from various areas of specialization within relevant scientific, education, or extension fields; (c) the need to include as reviewers other experts (e.g.,

producers, range or forest managers/operators, and consumers) who can assess relevance of the applications to targeted audiences and to program needs; (d) the need to include as reviewers experts from a variety of organizational types (e.g., colleges, universities, industry, state and Federal agencies, private profit and non-profit organizations) and geographic locations; (e) the need to maintain a balanced composition of reviewers with regard to minority and female representation and an equitable age distribution; and (f) the need to include reviewers who can judge the effective usefulness to producers and the general public of each application.

B. Evaluation Factors

The evaluation criteria below will be used in reviewing applications submitted in response to this RFA:

The evaluation criteria identified in 7 CFR 3415.15 will be used in reviewing applications submitted in response to this RFA. Applications for funding a scientific research conference grant will be evaluated on the following criteria: choice of topics and selection of speakers; general format of the conference, especially with regard to its appropriateness for fostering scientific exchange and/or public understanding; provisions for wide participation from the scientific and regulatory community and others as appropriate; qualifications of the organizing committee and appropriateness of invited speakers to the topic areas being covered; and appropriateness of the budget requested and qualifications of project personnel. All applications are considered together in making award decisions. However, no more than two conference grants will be awarded.

C. Conflicts of Interest and Confidentiality

During the peer evaluation process, extreme care will be taken to prevent any actual or perceived conflicts of interest that may impact review or evaluation. For the purpose of determining conflicts of interest, the academic and administrative autonomy of an institution shall be determined by reference to the 2002 Higher Education Directory, published by Higher Education Publications, Inc., 6400 Arlington Boulevard, Suite 648, Falls Church, Virginia 22042. Phone: (703) 532-2300. Web site: http://www.hepinc.com.

Names of submitting institutions and individuals, as well as application content and peer evaluations, will be kept confidential, except to those involved in the review process, to the extent permitted by law. In addition, the identities of peer reviewers will remain confidential throughout the entire review process. Therefore, the names of the reviewers will not be released to applicants.

PART V--AWARD ADMINISTRATION

A. General

Within the limit of funds available for such purpose, the awarding official of CSREES shall make grants to those responsible, eligible applicants whose applications are judged most meritorious under the procedures set forth in this RFA. The date specified by the awarding official of CSREES as the effective date of the grant shall be no later than September 30 of the Federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. It should be noted that the project need not be initiated on the grant effective date, but as soon thereafter as practical so that project goals may be attained within the funded project period. All funds granted by CSREES under this RFA shall be expended solely for the purpose for which the funds are granted in accordance with the approved application and budget, the regulations, the terms and conditions of the award, the applicable Federal cost principles, and the Department's assistance regulations (parts 3015 and 3019 of 7 CFR).

B. Organizational Management Information

Specific management information relating to an applicant shall be submitted on a one-time basis as part of the responsibility determination prior to the award of a grant identified under this RFA, if such information has not been provided previously under this or another CSREES program. CSREES will provide copies of forms recommended for use in fulfilling these requirements as part of the preaward process. Although an applicant may be eligible based on its status as one of these entities, there are factors which may exclude an applicant from receiving Federal financial and nonfinancial assistance and benefits under this program (e.g., debarment or suspension of an individual involved or a determination that an applicant is not responsible based on submitted organizational management information).

C. Award Document and Notice of Award

The grant award document shall include at a minimum the following:

(1) Legal name and address of performing organization or institution to whom the Administrator has awarded a grant under the terms of this request for applications;

(2) Title of project;

(3) Name(s) and institution(s) of PD’s chosen to direct and control approved activities;

(4) Identifying grant number assigned by the Department;

(5) Project period, specifying the amount of time the Department intends to support the project without requiring recompetition for funds;

(6) Total amount of Departmental financial assistance approved by the Administrator during the project period;

(7) Legal authority(ies) under which the grant is awarded;

(8) Appropriate Catalog of Federal Domestic Assistance (CFDA) number;

(9) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the grant award; and

(10) Other information or provisions deemed necessary by CSREES to carry out its respective granting activities or to accomplish the purpose of a particular grant.

The notice of grant award, in the form of a letter, will be prepared and will provide pertinent instructions or information to the grantee that is not included in the grant award document.

PART VI--ADDITIONAL INFORMATION

A. Access To Review Information

Copies of reviews, not including the identity of reviewers, and a summary of the panel comments will be sent to the applicant PD after the review process has been completed.

B. Use of Funds; Changes

1. Delegation of Fiscal Responsibility

Unless the terms and conditions of the grant state otherwise, the grantee may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of grant funds.

2. Changes in Project Plans

a. The permissible changes by the grantee, PD(s), or other key project personnel in the approved project grant shall be limited to changes in methodology, techniques, or other similar aspects of the project to expedite achievement of the project's approved goals. If the grantee or the PD(s) is uncertain as to whether a change complies with this provision, the question must be referred to the Authorized Departmental Officer (ADO) for a final determination. The ADO is the signatory of the award document, not the program contact.

b. Changes in approved goals or objectives shall be requested by the grantee and approved in writing by the ADO prior to effecting such changes. In no event shall requests for such changes be approved which are outside the scope of the original approved project.

c. Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the grantee and approved in writing by the ADO prior to effecting such changes.

d. Transfers of actual performance of the substantive programmatic work in whole or in part and provisions for payment of funds, whether or not Federal funds are involved, shall be requested by the grantee and approved in writing by the ADO prior to effecting such transfers, unless prescribed otherwise in the terms and conditions of the grant.

e. Changes in Project Period: The project period may be extended by CSREES without additional financial support, for such additional period(s) as the ADO determines may be necessary to complete or fulfill the purposes of an approved project, but in no case shall the total project period exceed five years. Any extension of time shall be conditioned upon prior request by the grantee and approval in writing by the ADO, unless prescribed otherwise in the terms and conditions of a grant.

f. Changes in Approved Budget: Changes in an approved budget must be requested by the grantee and approved in writing by the ADO prior to instituting such changes if the revision will involve transfers or expenditures of amounts requiring prior approval as set forth in the applicable Federal cost principles, Departmental regulations, or grant award.

C. Expected Program Outputs and Reporting Requirements

Reporting requirements will be identified in the Terms and Conditions of the grant award.

D. Applicable Federal Statutes and Regulations

Several Federal statutes and regulations apply to grant applications considered for review and to project grants awarded under this program. These include, but are not limited to:

7 CFR Part 1.1--USDA implementation of the Freedom of Information Act.

7 CFR Part 3--USDA implementation of OMB Circular No. A-129 regarding debt collection.

7 CFR Part 15, subpart A--USDA implementation of Title VI of the Civil Rights Act of 1964, as amended.

7 CFR Part 3015--USDA Uniform Federal Assistance Regulations, implementing OMB directives (i.e., OMB Circular Nos. A-21 and A-122) and incorporating provisions of 31 U.S.C. 6301-6308 (formerly the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. No. 95-224), as well as general policy requirements applicable to recipients of Departmental financial assistance.

7 CFR Part 3017--USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants).

7 CFR Part 3018--USDA implementation of Restrictions on Lobbying. Imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans.

7 CFR Part 3019--USDA implementation of OMB Circular A-110, Uniform Administrative Requirements for Grants and Other Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

7 CFR Part 3052--USDA implementation of OMB Circular No. A-133, Audits of States, Local Governments, and Non-profit Organizations.

7 CFR Part 3407--CSREES procedures to implement the National Environmental Policy Act of 1969, as amended.

29 U.S.C. 794 (section 504, Rehabilitation Act of 1973) and 7 CFR Part 15b (USDA implementation of statute)-- prohibiting discrimination based upon physical or mental handicap in Federally assisted programs.

35 U.S.C. 200 et seq.--Bayh-Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in Federally assisted programs (implementing regulations are contained in 37 CFR Part 401).

C. Confidential Aspects of Applications and Awards

When an application results in a grant, it becomes a part of the record of CSREES transactions, available to the public upon specific request. Information that the Secretary determines to be of a confidential, privileged, or proprietary nature will be held in confidence to the extent permitted by law. Therefore, any information that the applicant wishes to have considered as confidential, privileged, or proprietary should be clearly marked within the application. The original copy of an application that does not result in a grant will be retained by the Agency for a period of one year. Other copies will be destroyed. Such an application will be released only with the consent of the applicant or to the extent required by law. An application may be withdrawn at any time prior to the final action thereon.

D. Regulatory Information

For the reasons set forth in the final Rule-related Notice to 7 CFR part 3015, subpart V (48 FR 29114, June 24, 1983), this program is excluded from the scope of the Executive Order 12372 which requires intergovernmental consultation with State and local officials. Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collection of

information requirements contained in this Notice have been approved under OMB Document No. 0524-0039.

E. Definitions

Please refer to 7 CFR 3415.2 for the applicable definitions for this grant program.